STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF RADIATION PROTECTION
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May 4, 2010

The Honorable Edward J. Markey
Congress of the United States
House of Representatives
Subcommittee on Energy and Environment
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Congressman Markey:

This letter is in response to your March 18, 2010, request for information regarding Washington's oversight of the treatment of medical patients with radioisotopes. We asked for clarification to your original request which you provided on March 26, 2010. Based on our current understanding of your request, we are in the process of collecting the information you require in accordance with the Washington State Public Records Act.

Enclosed with this letter is our initial response to the questions you asked and the documents referenced in our response. Several of your questions require an extensive and time-consuming review of records. Approximately 500 inspection reports are under review now, and numerous files of individual staff will need to be searched as well. We expect to complete our search by June 30, 2010. At that time we will send our remaining responses.

If you need additional information or require clarification, please do not hesitate to contact me via phone at (360) 236-3210 or by email at gary.robertson@doh.wa.gov.

Sincerely,

Gary Robertson

Gary Robertson
Director

Enclosures

1. How many I-131 licensee facilities are overseen by your state?

We currently have 49 licensees authorized for I-131 therapy.

2. How often does your state perform sampling inspections (sic) each of these I-131 licensee facilities?

Our therapy facility inspections are currently performed on an annual basis.

3. What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Licensee compliance is determined through performance-based review of activities [as required by US Nuclear Regulatory Commission (NRC)], independent measurements, staff interviews, and select record review. Our inspection program is modeled on the NRC inspection program.

Enclosed are a copies of 1) the NRC Inspection Manual, "Inspection Procedure 87131, Nuclear Medicine Programs, Written Directive Required," 2) our Department of Health Radioactive Materials Section "Routine Inspection Procedure," and 3)our inspection report attachment specific to Radiopharmaceutical Therapy.

4. NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 mCi of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes per day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and, for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles, to wipe down the telephone with paper towels and then discard the paper towels, etc. What instructions has your state given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

All our medical licensees who administer radiopharmaceutical therapy must comply with the provisions of the NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials, 1997." We believe Regulatory Guide 8.39 covers the same concerns as NCRP 155 although the specific time details are left to the physician to determine as part of medical practice.

Enclosed is a copy of the NRC Regulatory Guide 8.39.

5. In the past ten years how many times has your state, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?

This is not part of the current inspection process. We do not believe this has ever been done as part of our inspection program. However, a review of past records is necessary to determine if

this has ever occurred. We are currently searching through approximately 500 inspection reports to determine our response. We expect to provide a response by June 30, 2010.

6. In the past ten years how many times has your state, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?

This is not part of the current inspection process. We do not believe this has ever been done as part of our inspection program. A review of past records is necessary to determine if this has ever occurred. We are currently searching through approximately 500 inspection reports to determine our response. We expect to provide a response by June 30, 2010.

7. In the past ten years how many times has your state identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.

Again, a review of past records is necessary to determine if this has ever occurred. We are currently searching through approximately 500 inspection reports to determine response. We expect to provide a response by June 30, 2010.

8. In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require knowledge of the layout of the hotel, and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of the wall. Do you agree?

We discourage our licensees from recommending a hotel stay immediately after a treatment.

9. Has your state ever attempted to determine how many patients treated with I-131 are: a) sent home, b) sent to a hotel, or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?

No, we have not identified a need to collect this information during an inspection.

10. In patients with doses in excess of the default limits, has your state ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your state ever encountered situations where individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.

Yes, our inspections of medical licensees cover review of therapy record. This includes required analysis of the patient's living situation as well as dose calculations to ensure members of the public are not exposed to limits in excess of those allowed by Regulatory Guide 8.39.

A review of past records is necessary to fully answer your question. We expect to provide a response by June 30, 2010.

11. What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?

We require our licensees to actively discourage all patients from going anywhere but directly home. Therefore, we have no rules for patient instructions that address information for patients to provide to hotel management.

12. Has your state ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.

Yes. Enclosed is a copy of our advisory dated March 26, 2009.

13. Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?

No. Section 246-221-001 of the Washington Administrative Code (WAC) specifically states that the limits in this chapter (which includes reporting limits) do not apply to exposure from individuals administered radioactive material and released under chapter 246-240 WAC.

14. Please provide copies of all correspondence, including emails, letters, meeting or telephone notes, or other materials between your state and the NRC related to the release of patients who have been treated with radionuclides.

An exhaustive review of our staff and office records is necessary to gather this information. We expect to provide a response by June 30, 2010.

15. Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.

We are currently searching through approximately 500 inspection reports to determine our response. We expect to provide a response by June 30, 2010.

NRC INSPECTION MANUAL

INSPECTION PROCEDURE 87131

NUCLEAR MEDICINE PROGRAMS,
WRITTEN DIRECTIVE REQUIRED

PROGRAM APPLICABILITY: 2800

87131-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

87131-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The NRC Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with NRC regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and uses, the inspector should contact NRC regional management as soon as practicable to independently verify that such use is authorized under NRC regulatory requirements. If further verification of such use is needed, the region should contact NMSS for further guidance.

87131-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be

survey instruments have been calibrated in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21.

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by NRC regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The

l. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks , if any, are consistent with the form and quantity restrictions of NRC regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within NRC regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee.

For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA).".

03.02 Shielding of Licensed Material

In an application for a license, a licensee must commit to develop, implement, and maintain procedures under 10 CFR 20.1101 and 10 CFR 20.1301 for safe use of unsealed byproduct material. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by 10 CFR 35.69.

inspector determines that a worker had exceeded an NRC regulatory limit, the inspector should immediately contact NRC regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation and Surveys

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NRC regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

(a) The radiation survey instruments have been calibrated in accordance with10 CFR 35.61;

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, "dry runs" for more complex or hazardous operations, and authorized nuclear pharmacists instruction in the preparation of drugs.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that for those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to NRC regulatory requirements.

have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and NRC regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with NRC regulatory requirements and the licensee's license.

In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under 10 CFR Part 35 license, and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation

30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded NRC regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NRC regulatory limits, the inspector should immediately contact NRC regional management for further guidance.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether

and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embry/fetus or a nursing child, etc.

From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to NRC and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for followup and compliance to the appropriate NRC regulatory requirements.

j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular NRC requirement.

k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently

#2

Routine inspection Procedure

Pre-Inspection Activities

Determine if announced/unannounced
If announced call and notify and/or schedule

Logistics
Locate address – review previous reports or use internet mapping service as necessary.
If traveling by air or by car follow correct admin procedure

Gather needed materials as needed, including:
Locate address(es) - Initial inspection should visit all use locations listed on the license
Identification badge
Calibrated Radiation Detection Instruments (extra batteries are recommended)
Check Source
Inspection documents
inspection and field forms
copy of license
copy of the technical assistance form completed at new license delivery
Regulations
Dosimetry
Business cards
Pager
Cell phone
Extra CRAM (Caution Radioactive Materials) posting,
RHF-3 "Notice to Employees"
Radiation emergency procedure posters.
Appropriate personal protective equipment (PPE)
Sample collection materials

Review Previous Inspection report(s) and license.

Inspection Performance

Opening, including as appropriate:
Emphasize purpose of routine inspection
Point out any areas of focus (generally any prior items of non-compliance) or program elements of concern
Request people to interview and documents/areas you want to look at
Ask if any changes since the last inspection

Field form/ letter
Emphasize license performance items of non-compliance
Any repeat issues
Items that may be significant in future inspections
Program elements of concern
.
Recommendations
Follow-Up Inspections if applicable

Post Inspection Activities

Fill out proper inspection forms
Write compliance letter if applicable
If a follow-up inspection will be required, be sure that a non-compliance letter is drafted, outlining the requirements, including the fee structure for 2nd follow-up inspection, per the most recent revision of WAC 246-254-120.
Attach any documents gathered at site
Fill out and attach QA sheet.
Turn in report and attachments
Send compliance letter if applicable
Send any other items requested by licensee during inspection (Postings, RHF-3 forms, etc.)
Send wipe samples to lab with the required paperwork
Make calls to management if they were not available for closing, if necessary.

(#3)

RADIOPHARMACEUTICAL THERAPY

B-13

LICENSEE:	DATE OF INSPECTION:
AUTHORIZED USERS AND/OR NUCLEAR MED TECH'S WHO ACTUALLY ADMINISTER THERAPY DOSES:	

THERAPY	I – 131 ☐	Sr – 89 ☐	P – 32 ☐	OTHER - ☐ _____
Inpatient/Year	_____	_____	_____	_____
Outpatient/Year	_____	_____	_____	_____
Maximum Dose	_____mCi	_____mCi	_____mCi	_____
Average Dose	_____mCi	_____mCi	_____mCi	_____

Proper Beta shielding for administration + storage of Sr^{89} P^{32} and/or otherBeta-Emitters? Yes ☐ No ☐ N/A ☐

Beta-Emitters are all unit-dose and assayed by nuclear Pharmacy? Yes ☐ No ☐ N/A ☐

Or Licensee has instituted and documented adequate Beta-Emitter dose assay program on-site. Yes ☐ No ☐ N/A ☐

Liquid ^{131}I doses are vented Yes ☐ No ☐ N/A ☐, **and** are administered as required. Yes ☐ No ☐ N/A ☐

In-patient(s) present during inspection? Yes ☐ No ☐ **(PRECLUDES PATIENT/ROOM INDEPENDENT SURVEY)?**

INSPECTOR SURVEY:	Instrument – Make/Model _____	S/N _____	Latest Calib _____	Background _____mr/hr
	Battery Check Okay? Yes ☐ No ☐	Response Check Okay? Yes ☐ No ☐		
DOSE RATE	Maximum One Meter from Patient _____mr/hr	With Shield ☐	Without Shield ☐ _____	
	Doorway of patient room _____mr/hr	Adjacent Room(s) and/or Area(s) _____mr/hr		
CONTAMINATION	Background _____CPM	Make/Model _____	S/N _____	Latest Calib _____
	Battery Check Okay? Yes ☐ No ☐	Response Check Okay? Yes ☐ No ☐		
	Contamination Noted: None ☐			

RECORDS

Patient chart(s) examined? Yes ☐ No ☐ _____

All **QMP** requirements followed? Yes ☐ No ☐ _____

Initial survey documented? Yes ☐ No ☐ **If yes:** Patient ☐ Room ☐ Environ/adjacent areas ☐

Proper instructions for nurses and visitors? Yes ☐ No ☐

Nurse Dosimetry Program adequate and in compliance with license conditions and regulations? Yes ☐ No ☐ N/A ☐

Proper and timely bioassay (I^{131} use only) for **all** who require Bioassay? Yes ☐ No ☐ N/A ☐

Adequate and documented room release survey(s)? Yes ☐ No ☐

Posting and labeling of rooms, areas and/or containers adequate? Yes ☐ No ☐

Patients remain hospitalized until at approved release limits? Yes ☐ No ☐ N/A ☐

Licensee Meter(s)	Make/Model _____	☐ /See Main Report	S/N _____	Latest Calib _____	Responds to Radiation Yes ☐ No ☐
	Adequate Battery? Yes ☐ No ☐	Adequate Range Yes ☐ No ☐		Proper Probe? Yes ☐ No ☐	

Additional Comments/Notes

Signature	Date

2-2006 NJB

#4

U.S. NUCLEAR REGULATORY COMMISSION April 1997

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.39

(Draft was DG-8015)

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Section 35.75, "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants," in 10 CFR Part 35, "Medical Use of Byproduct Material," permits licensees to "authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

Further, 10 CFR 35.75(b) requires that the licensee "provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include (1) guidance on the interruption or discontinuation of breast-feeding and (2) information on the consequences of failure to follow the guidance."

In addition, 10 CFR 35.75(c) requires that the licensee "maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calcu-Bated by (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less Than 0.25 at 1 meter, (3) using the biological or effective half-life, or (4) considering the shielding by tissue."

In 10 CFR 35.75(d), the licensee is required to "maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem)."

In this guide, the individual to whom the radioactive material has been administered is called the "patient."

This guide provides guidance to the licensee on determining (1) when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material, (2) when instructions to the patient are required by 10 CFR 35.75(b), and (3) when records are required by 10 CFR 35.75(c) and (d) to be generated and maintained. The guide lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

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for most radiopharmaceuticals (less than a few percent) relative to the external gamma dose (see Section B.3, "Internal Dose," of Appendix B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Regulatory Position 1.1, "Release of Patients Based on Administered Activity."

C. REGULATORY POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using conservative assumptions of (1) administered activity, (2) physical half-life, (3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and (4) no shielding by tissue. The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Appendix B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child as discussed in Regulatory Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.32 and 35.53.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, a record is required by 10 CFR 35.75(c) because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table 1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Regulatory Positions 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5-millisievert (0.5-rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10{,}000$ cm^2.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able

to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Appendix B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

2. INSTRUCTIONS

2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.[1] Licensees may use Column 1 of Table 2 to determine the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Regulatory Position 2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

The activities or dose rates in Table 2 may be used for determining when instructions must be given. When patient-specific calculations (as described in Appendix B) are used, instructions must be provided if the calculation indicates a dose that is greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation 2 or 3, as appropriate, may be used.

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After their Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if the patient was administered a radiopharmaceutical with an activity above the value stated in Column.1 of Table 3, instructions on discontinuation or on the interruption period for breast-feeding and the consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 percent of the administered activity is excreted in the breast milk (Ref. 2). The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. However, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following.

[1] The NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

Table 3. Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breast Feeding an Infant or Child					
Radiopharmaceutical	**COLUMN 1 Activity Above Which Instructions Are Required**		**COLUMN 1 Activity Above Which a Record Is Required**		**COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding***
	(MBq)	**(mCi)**	**(MBq)**	**(mCi)**	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 mIBG	70	2	400	10	24 hr for 370 MBq (10 mCi) 12 hr for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 Hr for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq (12 mCi)
Tc-99m DISADA	1,000	30	6,000	150	
Tc-99m Glucoheptonate	1,000	30	6,000	150	
Tc-99m HAM	400	10	2,000	50	
Tc-99m MIBI	1,000	30	6,000	150	
Tc-99m MDP	1,000	30	6,000	150	
Tc-99m PYP	900	25	4,000	120	
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	6 Hr for 740 MBq (20 mCi)
Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	
Tc-99m Sulfur Colloid	300	7	1,000	35	6 Hr for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1,000	30	6,000	150	
Tc-99m MAG3	1,000	30	6,000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hr for 1,100 MBq (5 mCi) [sic] 12 hr for 440 MBq (2 mCi) [sic]

breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(l) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Permanent Implants

For patients who have received permanent implants, additional instructions may include the following.

> A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days.
>
> - Stay at a distance of _____ feet from _____.
> - Maintain separate sleeping arrangements.
> - Minimize time with children and pregnant women.
> - Do not hold or cuddle children.
> - Avoid public transportation.
> - Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
> - If you find a seed or pellet that falls out:
>   - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
>   - Place the container with the seed or pellet in a location away from people,
>   - Notify one of the persons listed in this instruction.

3. RECORDS

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table 1. However, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information.

(1) For Immediate Release of a Patient Based on a Patient-Specific Calculation: The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Appendix B of this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

(2) For Immediate Release of a Patient Based on Measured Dose Rate: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

(3) For Delayed Release of a Patient Based on Radioactive Decay Calculation: The time of the administration, date and time of release, and the results of the decay calculation.

(4) For Delayed Release of a Patient Based on Measured Dose Rate: The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping re-

Table 4. Summary of Release Criteria, Required Instructions to Patients, and Records To Be Maintained				
PATIENT GROUP	**BASIS FOR RELEASE**	**CRITERIA FOR RELEASE**	**INSTRUCTIONS NEEDED?**	**RELEASE RECORDS REQUIRED?**
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes - if administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity ≤ Column 1 of Table 1	Yes - if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table 1	Yes - if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes - if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table 3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

APPENDIX A

Table A-1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide[1]	Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi-h at 1 cm)	Radionuclide[1]	Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi-h at 1 cm)
Ag-111	7.45	0.150	Pd-103 implant	16.96	0.86[5]
Au-198	2.696	2.3	Re-186	3.777	0.2
Cr-51	27.704	0.016	Re-188	0.708	0.26
Cu-64	0.529	1.2	Sc-47	3.351	0.56
Cu-67	2.578	0.58	Se-75	119.8	2.0
Ga-67	3.261	0.753	Sm-153	1.946	0.425
I-123	0.55	1.61	Sn-117m	13.61	1.48
I-125	60.14	1.42	Sr-89	50.5	NA[6]
I-125 implant	60.14	1.11[4]	Tc-99m	0.251	0.756
I-131	8.04	2.2	Tl-201	3.044	0.447
In-111	2.83	3.21	Y-90	2.67	NA[6]
Ir-192 implant	74.02	4.59[4]	Yb-169	32.01	1.83
P-32	14.29	NA[6]			

[1] Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

[2] K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/l-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

[3] Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

[4] R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into ac- count the attenuation of gamma rays within the implant capsule itself.

[5] A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

[6] Not applicable (NA) because the release activity is not based on beta emissions.

- Do not travel on a prolonged automobile trip with others for at least the first 2 days,
- Have sole use of a bathroom for at least the first 2 days,
- Drink plenty of fluids for at least the first 2 days.

- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as,
  - Follow the instructions for E = 0.25 above,
  - Live alone for at least the first 2 days,
  - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroid al and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient has been provided with instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-l. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_P\ E}{r^2}$$

Since the patient has been provided with instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\ (2.2\ R \cdot cm^2/mCi \cdot hr)\ (60\ mCi)\ (8.04\ d)\ (0.125)}{(100\ cm)^2}$$

$D(\infty)$ = 4.59 millisieverts (0.459 rem)

Since the dose is less than 5 millisieverts (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained pursuant to 10 CFR 35.75(c) because an occupancy factor less than 0.25 at 1 meter was used.

B.2 EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as:

$$T_{eff} = \frac{T_b\ x\ T_p}{T_b + T_p} \qquad \text{(Equation B-2)}$$

Where T_b = biological half-life of the radionuclide

T_P = physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

$$T_{1eff} = \frac{T_{b1}\ x\ T_p}{T_{b1} + T_p} \qquad \text{(Equation B-3)}$$

$$T_{2eff} = \frac{T_{b2}\ x\ T_p}{T_{b2} + T_p} \qquad \text{(Equation B-4)}$$

Where T_{b1} = biological half-life for extrathyroidal iodide

T_{b2} = biological half-life of iodide following uptake by the thyroid

T_P = physical half-life of iodine-131.

However, simple exponential excretion models do not account for (a) the time for the iodine-131 to be absorbed from the stomach to the blood and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this guide makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the

occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations," of this Appendix B).

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2)(200)}{(100\,cm)^2}\{(0.75)(8.04)(0.8)(1 - e^{-0.693(033)/8.04}) + e^{-0.693(0.33)/8.04}(0.25)(0.95)(0.32) + e^{-0.693(0.33)/8.04}(0.25)(0.05)(7.3)\}$$

$D(\infty)$ = 4.53 millisieverts (0.453 rem)

Therefore, thyroid cancer patients administered 7,400 megabecquerels (200 millicuries) of iodine-131 or less would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, F_2 = 0.05, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to a individual exposed to a patient who has been administered 2,035 megabecquerels (55 millicuries) of iodine-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table A-l, and Table B-l to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2)(55)}{(100\,cm)^2}\{(0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04}) + e^{-0.693(0.33)/8.04}(0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04}(0.25)(0.80)(5.2)\}$$

$D(\infty)$ = 4.86 mSv (0.486 rem)

Therefore, hyperthyroid patients administered 2,035 megabecquerels (55 millicuries) of iodine-131 would not have to remain under licensee control and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, F_2 = 0.8, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 INTERNAL DOSE

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

$$Di = Q(10^{-5})(DCF) \qquad \text{(Equation B-B)}$$

Where Di = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems

= Activity administered to the patient in millicuries

10^{-5} = Assumed fractional intake

DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases

REFERENCES FOR APPENDIX B

B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, NUREG-1492, February 1997.*

B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,* Federal Guidance Report No. 11, U. S. Environmental Protection Agency, Washington, DC, 1988.

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?'),"
Health Physics, Volume 39, Number 6, 1980.

B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients-The Contamination Hazard," *British Journal of Radiology,* Volume 43, 1970.

B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health,* Volume 68, Number 3, 1978.

B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

*Copies may be purchased at current rates from the U. S. Government Printing Office, P. O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249; or from the National Technical Information service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies of drafts are also available for inspection and copying for a fee from the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634- 3343.

REGULATORY ANALYSIS

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997), provides the regulatory basis for this guide and examines the costs a benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P. O. Box 37082, Washington DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

#5

STATE OF WASHINGTON
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INFORMATION NOTICE

March 26, 2009

TO: All Medical Licensees Authorized Therapeutic Use of Iodine-131

FROM: C. DeMaris
Medical Licensing

SUBJECT: **Release of Therapy Patients Administered Iodine-131**

Please discourage the use of hotels following treatment. It has recently been brought to our attention that Regulatory Guide 8.39 does not specifically reference where a patient should reside when released after a therapeutic dose of Iodine-131. It is presumed that most, if not all, patients go home although there is nothing in the Guide preventing a patient from using a hotel.

A specific public complaint has been raised that a patient using a hotel immediately following release could, under certain circumstances, present an unnecessary risk of exposure to others, especially infants and children. We believe the concern is consistent with the International Commission on Radiological Protection's Publication 94, *Release of Patients after Therapy with Unsealed Radionuclides*. This publication cautions that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

At present, it is our understanding that you neither advise nor encourage the use of a hotel. Nevertheless, we believe it is prudent to eliminate this potential.

We recommend that you actively discourage patient use of hotels immediately after release.

This notice requires no specific response from you. If you have any questions, I can be reached at 360-236-3223.

Thank you for your time and cooperation.